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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,070	01/06/2001	Paul D. Taylor	P-514	6470

7590
William B. Walker
Transgenomic, INC.
2032 Concourse Drive
San Jose, CA 95131

08/26/2002

EXAMINER

GUNTER, DAVID R

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,070

Applicant(s)

TAYLOR, PAUL D.

Examiner

David R. Gunter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, 64-68, and 72, drawn to a chromatographic method for separating heteroduplex and homoduplex DNA molecules, classified in class 220, subclass 661.
- II. Claims 43-51, drawn to an aqueous mobile phase, classified in class 252, subclass 364.
- III. Claims 52-63, drawn to a composition of a mobile phase and an anion-exchange solid, classified in class 220, subclass 661.
- IV. Claims 69-71, drawn to a method of detecting DNA mutations, classified in class 220, subclass 661.

1. Groups II and III are related to Groups I and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case products (the aqueous mobile phase of Group II and the composition of Group III) can be used in a number of processes materially different from the separation of homoduplex and heteroduplex DNA molecules (Group I) or the identification of DNA mutations (Group IV) including purification of nucleic acids from a sample containing a plurality of biomolecules and fractionation of proteins.

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2. Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I recites a method for the chromatographic separation of heteroduplex and homoduplex DNA molecules. Group IV recites the additional method steps of heating both the sample to be assayed and a control to a temperature sufficient to “completely” denature the nucleic acids, cooling the nucleic acids, determining the “heteromutant site separation temperature,” and performing chromatography at this specific temperature (Claim 69). These additional method steps represent a substantial difference between the mode of operation of Groups I and IV. In addition, the function and effect of Group I (separation of nucleic acid molecules) are substantially different from the function and effect of Group IV (identification of mutated DNA) because they achieve different final results and are employed for different purposes.

3. Groups II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (the mobile phase and anion-exchange resin of Group III) as claimed does not require the particulars of the subcombination (the mobile phase of Group II) as claimed because other solutions which fall outside of the limitations of Claims 43-51 can also be combined with an anion-exchange resin to accomplish the method of Group I. The

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subcombination has separate utility such as acting as a mobile phase for chromatography using a variety of other resins or for the separation of other molecules than nucleic acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701.

The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.



David R. Gunter, DVM, PhD
August 21, 2002


STEPHANIE W. ZITOMER
PRIMARY EXAMINER